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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Bayer Healthcare Pharmaceuticals, Inc.,

Plaintiff,

vs.

RJ Health Systems International, LLC,

Defendant.

No. 2:15-cv-06952-KM-MAH

DEFENDANT RJ HEALTH SYSTEMS INTERNATIONAL, LLC'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT

ORAL HEARING REQUESTED

Motion Date: October 3, 2016

Document Filed Electronically

TABLE OF CONTENTS

Page(s)

TABLE OF CONTENTS (continued)

Page(s)

TABLE OF AUTHORITIES

Page

CASES:

STATUTES AND OTHER AUTHORITIES:

Defendant RJ Health Systems International, LLC ("RJ Health") respectfully submits this memorandum of law in support of its motion to dismiss the First Amended Complaint filed by Plaintiff Bayer Healthcare Pharmaceuticals, Inc. ("Bayer" or "Plaintiff") on August 1, 2016.

Plaintiff's First Amended Complaint makes another attempt to plead a cause of action for negligent misrepresentation, following the Court's dismissal of that cause of action as originally pled in its decision dated June 30, 2016. For all the reasons stated below, Plaintiff has again been unable to state a cause of action for negligent misrepresentation, and its Fourth Cause of Action should therefore again be dismissed, this time with prejudice.

In addition, Plaintiff's Amended Complaint adds new and detailed allegations throughout the complaint which for the first time set out its contentions regarding how it claims to have been injured by the data contained on RJ Health's database. Specifically, Plaintiff now alleges that RJ Health's treatment of Liletta on its database caused health insurers and other payors to lower the reimbursement level that they would pay for Mirena, which in turn threatened to cause gynecologists and other health care providers to stop using Mirena, which in turn caused Plaintiff to lower its prices. Am. Compl. ¶¶ 43-46, 53-54.

These new allegations make abundantly clear that *all* of Plaintiff's claims are unsustainable as a matter of law. First, Plaintiff's effort to bring a claim under

the Lanham Act must fail. The false advertising provisions of the Lanham Act apply only to *advertising* for the defendant's goods and services, which RJ Health's database clearly is not. In addition, Plaintiff's new factual allegations make it apparent that Plaintiff lacks standing under the Lanham Act; the causal connection between RJ Health's conduct and Plaintiff's alleged injury as spelled out in the newly pled allegations is far too tenuous to comport with the "proximate cause" requirement of Lanham Act standing.

The Amended Complaint also makes clear that Plaintiff's state law claims are preempted by federal law. Plaintiff's newly-pleaded factual allegations illuminate that, at bottom, the claimed "misrepresentation" that forms the basis for all of Plaintiff's claims was RJ Health's placement of Liletta in the same Healthcare Common Procedure Coding System (HCPCS, pronounced "hic-pix") code as Mirena. *See* Am. Compl. ¶¶ 45, 52, 53. But federal law places exclusive responsibility for regulating HCPCS codes on the Centers for Medicare & Medicaid Services ("CMS") of the U.S. Department of Health and Human Service ("HHS"), not on private parties purporting to invoke state tort laws. And Plaintiff's new allegations make clear that RJ Health acted in compliance with CMS's coding decisions at all times. Plaintiff's state law claims therefore are preempted by federal law.

In addition, Plaintiff lacks standing to pursue its claim under the Connecticut Unfair Trade Practices Act, because Plaintiff does not fall within the narrow class of persons entitled to sue under that provision – consumers, competitors, and persons in a business relationship with the defendant. And Plaintiff's re-pled negligent misrepresentation claim also fails as a matter of law, because Plaintiff did not rely upon the challenged statements by RJ Health, and reliance *by the plaintiff* is a critical element of such a claim.

In short, Plaintiff's Amended Complaint should be dismissed in its entirety for failure to state a claim.

LEGAL STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

The Third Circuit espouses a two-part analysis in reviewing a complaint under Rule 12(b)(6). *See Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009); *see also In re Plavix Mktg., Sales Practices & Prods. Liab. Litig.*, 123 F. Supp. 3d 584, 593 (D.N.J. 2015). First, while a district court must accept all of the complaint's well-pleaded facts as true, it "may disregard any legal conclusions." *Fowler*, 578 F.3d at 210; *see also K.J. ex rel. Lowry v. Div. of Youth & Family*

Servs., 363 F. Supp. 2d 728, 738 (D.N.J. 2005) ("Legal conclusions offered in the guise of factual allegations . . . are given no presumption of truthfulness."). Second, "a [d]istrict [c]ourt must then determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.' " *Fowler*, 578 F.3d at 211 (quoting *Iqbal*, 556 U.S. at 679). In doing so, a court may consider the allegations of the complaint, exhibits attached to or specifically referenced in the complaint, and matters of public record. *See Pittsburgh v. W. Penn. Power Co.*, 147 F.3d 256, 259 (3d Cir. 1998).

The plausibility standard is only met "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. A court will not be able to draw such an inference when the plaintiff offers "[t]hreadbare recitals of the elements of a cause of action," "mere conclusory statements," or " 'naked assertion[s]' devoid of 'further factual enhancement.'" *Id.* (second alteration in original) (quoting *Twombly*, 550 U.S. at 557). Ultimately, "a complaint must do more than allege the plaintiff's entitlement to relief. A complaint has to show such an entitlement with its facts." *Fowler*, 578 F.3d at 211 (internal quotation marks omitted).

ARGUMENT

I. PLAINTIFF'S LANHAM ACT CLAIM (COUNT I) SHOULD BE DISMISSED.

A. RJ HEALTH'S DATABASE DOES NOT CONSTITUTE "COMMERCIAL ADVERTISING OR PROMOTION."

First and foremost, Plaintiff's false advertising claim should be dismissed because RJ Health's drug-information database does not constitute advertising.[1] It is well settled that the false advertising provision of the Lanham Act applies only to "commercial advertising or promotion." 15 U.S.C. § 1125(a)(1)(B); *see Navarra v. Marlborough Gallery, Inc.*, 820 F. Supp. 2d 477, 488 (S.D.N.Y. 2011); *CHW Grp., Inc. v. Better Bus. Bureau of N.J., Inc.*, No. 11-3261(JAP-TJB), 2012 WL 426292, at *3 (D.N.J. Feb. 8, 2012). As a result, a Lanham Act false advertising claim that does not properly allege "commercial advertising or promotion" must be dismissed. *Donini Int'l, S.p.A v. Satec (U.S.A.) LLC*, No. 03 Civ. 9471(CSH), 2004 WL 1574645, at *7 (S.D.N.Y. July 13, 2004).

In order to constitute "commercial advertising or promotion," the challenged statement must be: (1) commercial speech; (2) made for the purpose of influencing consumers to buy defendant's goods or services; and (3) disseminated sufficiently

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[1] While there are some cases holding that drug price lists can constitute advertising for drug companies whose products are listed on the databases, *see, e.g.*, *Mutual Pharm. Co., Inc. v. Watson Pharms, Inc.*, No. 09-5421 (GEB), 2010 WL 446132, at *5 (D.N.J. Feb. 8, 2010), those cases provide no support for any claim that a drug database constitutes advertising for the *publisher* of the database.

to the relevant purchasing public. *Boule v. Hutton*, 328 F.3d 84, 90-91 (2d Cir. 2003); *see also CHW Group*, 2012 WL 426292, at *3. A plaintiff's failure to adequately allege facts in support of any of these elements is fatal to its false advertising claim. *See, e.g.*, *Gentle Wind Project v. Garvey,* No. 04–103–P–C, 2004 WL 1946448, at *5–6 (D. Me. Sept. 2, 2004) (failure to allege factual support for one element of test entitles moving party to dismissal of Lanham Act claim); *Podiatrist Ass'n, Inc. v. La Cruz Azul de P.R., Inc.,* 332 F.3d 6, 18-20 (1st Cir. 2003) ("skimpy allegations" on commercial advertisement insufficient to survive dismissal); *Encompass Ins. Co. of MA v. Giampa*, 522 F. Supp. 2d 300, 311 (D. Mass. 2007) (conclusory allegations that defendant "has made false and misleading representations of fact in commercial advertising and promotion" insufficient to survive dismissal); *Imagine Medispa, LLC v. Transformations, Inc.*, 999 F. Supp. 2d 873, 881-82 (S.D.W. Va. 2014) (conclusory allegations regarding commercial advertising insufficient to survive dismissal).

Plaintiff cannot meet two of the three elements of commercial advertising here. First, the data contained in RJ Health's database does not constitute a statement made by RJ Health "for the purpose of influencing [Plaintiff's] customers to buy [Defendant]'s goods or services." CHW Grp., 2012 WL 426292, at *5. And second, Plaintiff has not articulated what the relevant market

supposedly is, let alone alleged that the challenged statements were sufficiently disseminated to that market.

1. The Data in RJ Health's Database Is Not Published for the Purpose of Influencing Customers to Buy RJ Health's Goods or Services.

In order to avoid dismissal, a Lanham Act plaintiff must adequately plead that the challenged statements were made "for the purpose of influencing [Plaintiff's] customers to buy [defendant's] goods or services." *CHW Grp.*, 2012 WL 426292, at *5. Plaintiff cannot do so here, because the database on which Plaintiff's claim is based *constitutes* RJ Health's product – not *advertising* designed to convince RJ Health's customers to buy its goods or services. *See* Am. Compl. ¶¶ 42-46.

In *CHW Group*, a company that sold home warranties alleged that the Better Business Bureau ("BBB") violated the Lanham Act's false advertising provision by assigning the plaintiff a low rating. *Id.* at *1-2. The court dismissed the plaintiff's Lanham Act claim on two alternative grounds, including that the challenged statements were not "made for the purpose of influencing [Plaintiff's] customers to buy [defendant's] goods or services." *Id.* at *5. Because the BBB's rating was not designed to steer customers to the BBB's website, the court held that the plaintiff failed to satisfy this element of the "commercial advertising and promotion test" and granted the defendant's motion to dismiss. *Id.*

The same principle requires dismissal here. The information contained in RJ Health's database constitutes the company's goods and services, much like a published book or magazine. It is not conveyed to consumers for the purposes of promoting RJ Health's products in the marketplace, and as such it is not advertising or promotion as a matter of law. *See Mitchell v. Joyner*, No. 14-0997-CV-ODS, 2015 WL 139326843 (W.D. Mo. Mar. 25, 2015) (rejecting Lanham Act claim relating to statements made in media broadcast, because broadcast did not constitute advertisement or promotion); *see also Gillette Co. v. Norelco Consumer Products Co.*, 946 F. Supp. 115, 1354 (D. Mass. 1996) ("Statements made inside the product's packaging, available to consumers only after the purchase has been made, do not affect the choice to purchase, that choice having been made at an earlier point.").

No doubt cognizant of the weakness of its false advertising claim, Plaintiff separately alleges in its complaint that RJ Health also has misrepresented the reliability of its database to customers by "claim[ing] in its commercial advertising and promotion that its drug information resources are accurate and based on published prices, when they clearly are not with respect to Liletta and Mirena." Am. Compl. ¶ 59. But as explained later in this brief, Plaintiff lacks standing to make this argument, because its alleged injury is not proximately caused by any alleged false statement regarding the database as a whole. *See, e.g., Wall &*

Assocs., Inc. v. Better Bus. Bureau of Centr. Va., Inc., No. 1:16-cv-119, 2016 WL 3087055 (E.D. Va. May 31, 2016) (dismissing Lanham Act complaint on proximate cause element of standing requirement, where plaintiff alleged that consumers relied on BBB's representations that its rating system was unbiased and objective, which in turn caused consumers to rely on reviews contained on website).

2. Plaintiff Has Not Alleged That RJ Health's Database is Sufficiently Disseminated To The Relevant Purchasing Public.

Plaintiff also has failed to properly allege another key element of the commercial advertising test – that the challenged statements were "disseminated sufficiently to the relevant purchasing public." *CHW Grp.*, 2012 WL 426292, at *3; *see also Fashion Boutique of Short Hills, Inc., v. Fendi USA, Inc.*, 314 F.3d 48, 57-58 (2d Cir. 2002) (dismissing Lanham Act claims where plaintiff failed to allege sufficient facts "to satisfy the requirement that representations be disseminated widely in order to constitute 'commercial advertising or promotion' under the Lanham Act") (citation omitted).

In order to avoid dismissal for failure to adequately plead this element, a plaintiff must allege both (1) "who comprises the relevant purchasing public;" and (2) "how many consumers within the relevant purchasing public received the advertisement." *Ameritox, Ltd. v. Millennium Labs., Inc.*, No. 8:11-cv-775-T-24-TBM, 2012 WL 33155, at *2 (M.D. Fla. Jan. 6, 2012). Lanham Act cases are

routinely dismissed where the plaintiff has failed to allege facts demonstrating that the challenged statements were sufficiently disseminated to the purchasing public. *See Infection Prevention Tech., LLC v. UVAS, LLC*, No. 10-cv-12371, 2011 WL 4360007, at *22 (E.D. Mich. July 25, 2011) (dismissing false advertising claim because plaintiff failed to "plead the relevant market," including "how many consumers in the relevant purchasing public" were contacted); *Sussman Automatic Corp. v. Spa World Corp.*, 15 F. Supp. 3d 258, 272 (E.D.N.Y. 2014) (dismissing Lanham Act claim where complaint "ma[de] no attempt to define or allege a 'relevant market' for purposes of the false advertising claim."). Factual averments demonstrating widespread dissemination within the relevant industry is a "normal concomitant of meeting this requirement." *Fashion Boutique*, 314 F.3d at 57.

Plaintiff has failed to comply with this requirement here. The Amended Complaint does not even identify the relevant market, let alone describe the extent of penetration of such market. Specifically, the Amended Complaint contains no allegations regarding the extent to which members of the relevant market received the challenged materials. Without any allegations as to the size of the relevant market or the extent of penetration by the challenged data, Plaintiff has failed to allege that the challenged representations have been "disseminated sufficiently to the relevant purchasing public." *CHW Grp.*, 2012 WL 426292, at * 3. At best, Plaintiff's assertions on this element are bare and conclusory – and therefore

insufficient to avoid dismissal. *See, e.g.*, *Installation Servs., Inc. v. Elec. Research, Inc.*, No. 04 C 6906, 2005 WL 645244, at *2 (N.D. Ill. Mar. 21, 2005) (dismissing Lanham Act claims where complaint failed to properly define market).

B. PLAINTIFF LACKS STANDING UNDER THE LANHAM ACT.

Plaintiff's false advertising claim also fails because Bayer lacks standing under the Lanham Act. In *Lexmark International, Inc. v. Static Control Components, Inc.,* 134 S. Ct. 1377 (2014), the Supreme Court made clear that in order to establish standing, a Lanham Act plaintiff must allege both that it falls within the zone of interest of the statute *and* that its injuries were proximately caused by the defendant's advertising. *Lexmark* involved a dispute between a manufacturer of laser printers and cartridges, and a manufacturer of the components necessary to remanufacture those same cartridges. *Id.* at 1383-84. The Supreme Court held that (1) "to come within the zone of interests in a suit for false advertising under § 1125(a), a plaintiff must allege an injury to a commercial interest in reputation or sales," and (2) to establish proximate cause, a plaintiff "must show economic or reputational injury *flowing directly* from the deception wrought by the defendant's advertising . . . ." *Id.* at 1390-91 (emphasis added). While – as this Court noted in its June 30 decision – the Supreme Court held that a party need not necessarily be a direct competitor in order to establish standing under the Lanham Act, the Court specifically noted that "a plaintiff who does not

compete with the defendant will often have a harder time establishing proximate causation." *Id.* at 1392. And the Court explained that the proximate cause requirement "is generally not made when the deception produces injuries to a fellow commercial actor that in turn affects the plaintiff." *Id.* at 1391.

Although the Court's June 30 opinion noted that the alleged misstatement in the price of Mirena "could affect Bayer's sales," June 30 Op. at 6, this alone is not enough to satisfy the proximate cause test, and the new factual allegations of Plaintiff's Amended Complaint make clear that Bayer is alleging precisely the type of indirect harm that the Supreme Court has held to be insufficient. Specifically, Plaintiff now asserts that, as a result of RJ Health's treatment of the coding for Liletta, "several health insurers and other payors lowered the reimbursement level they would pay for Mirena to $625." Am. Compl. ¶ 43. Plaintiff then alleges that the payors' conduct in lowering the reimbursement level "would essentially have forced [health care] providers to stop using Mirena." *Id.* ¶ 47. And that, Plaintiff alleges, in turn caused Plaintiff to voluntarily lower its prices. *Id.* ¶ 49. In other words, Plaintiff has argued that (1) RJ Health's inclusion of the lower-priced Liletta in code J7302 (2) caused insurance payors to lower their payment rates, which in turn (3) harmed healthcare providers such as gynecologists, (4) incentivizing them to use Liletta instead, and (5) causing Plaintiff to lower its prices preemptively. This extremely indirect chain of causation simply does not

satisfy the proximate cause requirement for standing under the Lanham Act, which requires a plaintiff to allege that its "economic or reputational injury flow[s] *directly* from deception wrought by the defendant's advertising." *Lexmark,* 134 S. Ct. at 1391 (emphasis added); *see Wall & Assocs.,* 2016 WL 3087055, at *2-3 (post-*Lexmark* case in which the court determined that the relationship between a consumer review business and a tax settlement business was "too flimsy" to support a Lanham Act claim).

Plaintiff's newly-clarified causation argument makes abundantly clear that its injury did not "flow directly" from RJ Health's actions. As a result, Plaintiff lacks standing under the Lanham Act.

II. PLAINTIFF'S STATE LAW CLAIMS (COUNTS II, III, AND IV) ARE PREEMPTED BY FEDERAL LAW.

Plaintiff's state law claims are preempted by federal law. The Supremacy Clause of Article VI of the Constitution invalidates state laws, including judicial decisions applying state tort or statutory laws, that conflict or interfere with Acts of Congress. *See Rose v. Ark. State Police*, 479 U.S. 1, 3 (1986); *see also Gibbons v. Ogden*, 22 U.S. 1, 82 (1824) (state laws which "interfere with, or are contrary to" federal laws are deemed preempted); *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) ("[S]tate law that conflicts with federal law is without effect.") (internal quotation marks and citation omitted). Moreover, "[w]here Congress has

delegated the authority to regulate a particular field to an administrative agency, the agency's regulations issued pursuant to that authority have no less preemptive effect than federal statutes." *Treasurer of N.J. v. U.S. Dep't of Treasury*, 684 F.3d 382, 406 (3d Cir. 2012) (internal quotation marks and citations omitted).

In its initial Complaint, Plaintiff went to great lengths to try to package its claims as though they hinge on the improper reporting of the wholesale acquisition cost ("WAC") for Mirena. However, at bottom, this case is about a coding decision. Plaintiff now admits that the disputed piece of data on RJ Health's database – the "code price" for J7302 – merely purports to reflect the WAC for the product in that code with the lowest WAC. *Compare* Am. Compl. ¶ 42 to Compl. ¶ 41. And the new allegations in the Amended Complaint make clear that Plaintiff's state law claims are premised on the assertion that RJ Health caused it harm by placing Liletta in what Plaintiff viewed to be the wrong HCPCS code, which is referred to as a "J Code." *See* Am. Compl. ¶ 45 (trumpeting that RJ Health was warned to treat Mirena and Liletta "as separate codes due to the different pricing and different durations," but RJ Health nonetheless "opted to code them both to J7302"); ¶ 52 (describing CMS's conduct in creating "two new J Codes distinguishing Mirena and Liletta based on length of approved duration); ¶ 53 (acknowledging that Plaintiff's concerns were resolved when CMS discontinued HCPCS Code J7302 and "created two new J Codes whose descriptors

distinguish the drugs based on approved duration"); *see also* Dkt. No. 45 at 8 ("RJ Health misleadingly conflated Liletta and Mirena by lumping them together under the same J Code."). And that, Plaintiff alleges, in turn resulted in an artificially low code price for the other product in J7302, Mirena. Am. Compl. ¶¶ 42-45, 52-54.

But federal law vests responsibility for overseeing Level II HCPCS codes with CMS, which has the exclusive authority to oversee the regulation of J Codes. 42 C.F.R. § 414.40(a). The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") required CMS to adopt standards for coding systems that are used for reporting health care transactions. Pursuant to this authority, CMS establishes uniform national Level II HCPCS codes (the codes that apply to products like Mirena and Litletta) and descriptors – the definition of what the code covers – for the codes. And federal law specifically mandates that – in order to promote national uniformity in health insurance coding – private health plans and health care providers must use these HCPCS codes in order to facilitate electronic billing. *See* 42 U.S.C. § 1320d-2(a)(1); 45 C.F.R. § 162.1000 - 1002.

As CMS has explained, "[t]he permanent national codes serve the important function of providing a standardized coding system that is managed jointly by private and public insurers. This standardized approach to developing a set of uniform codes provides a stable environment for claims submission and processing

. . . ."[2] Professional coders are directed to place products in the HCPCS code whose descriptor best matches the drug product at hand. "This system ensures uniform reporting on claims forms of items or services that are medical in nature. Such a standardized coding system is needed by public and private insurance programs to ensure the uniform reporting of services on claims forms by suppliers and for meaningful data collection."[3] *See also Aetna Health Inc. v. Carolina Analgesic, Inc.*, No. 13-7202 (NLH/AMD), 2016 WL 3410178, at *2 (D.N.J. June 16, 2016) (noting that federal regulations designate HCPCS codes as the "standard codes" to be used on private insurance claims forms). As a practical matter, this means that companies supplying payer organizations with health care claims information — including RJ Health — must use the HCPCS codes adopted by CMS as well.

If a drug manufacturer is unhappy with how health care providers are coding its drug, it can submit a request to CMS to modify the HCPCS Level II national

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[2] HCPCS Level II Coding Procedures, available at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/HCPCSLevelIICodingProcedures7-2011.pdf. This Court may take judicial notice of publicly-available regulatory materials and guidance documents prepared by CMS. *See, e.g., Oran v. Stafford,* 226 F.3d 275, 289 (3d Cir. 2000) (taking judicial notice of information contained in public SEC filings).

[3] HCPCS Level II Coding Procedures, available at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/HCPCSLevelIICodingProcedures7-2011.pdf.

code set.[4] There are three types of revisions that CMS can make to the HCPCS code set: (i) it can add a permanent code; (ii) it can change the language used to describe an existing code; or (iii) it can discontinue a code.[5] The HCPCS Workgroup will consider the request and issue a preliminary decision, followed by a final decision in November, to become effective the following January.

Plaintiff's real dispute, then, is with CMS, not RJ Health. Tellingly, Plaintiff admits that before suing RJ Health, it first lobbied CMS to revise the code descriptor for J7302 so that it would not apply to Liletta (or any other IUD other than Mirena). Am. Compl. ¶ 52. First, in 2014, CMS's HCPCS Workgroup denied Plaintiff's request that the descriptor for Code J7302 be revised to specifically reference Mirena, which Plaintiff sought in order to make clear that no other IUDs could be placed in that code.[6] Then, in response to Plaintiff's second request to make Code J7302 exclusive to Mirena, in May 2015, CMS's HCPCS Workgroup again "preliminarily recommended against any change to the code

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[4] HCPCS Level II Coding Procedures, at 6-7, available at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/HCPCSLevelIICodingProcedures7-2011.pdf.

[5] HCPCS Level II Coding Procedures, at 6-7 available at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/HCPCSLevelIICodingProcedures7-2011.pdf.

[6] *See* May 21, 2014 Public Meeting Summary, available at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2014-05-21-Drug-Summary.pdf.

descriptor for J7302 on the ground that the descriptor was sufficient to accurately describe Mirena." Am. Compl. ¶ 52. CMS took this action despite Bayer's plea that the "recent FDA approval of another Levonorgestrel-releasing 52 mg. IUD with a different duration [*i.e.*, Liletta] has created an urgent need for more specific HCPCS codes to distinguish among these products."[7]

Plaintiff now admits that after this lawsuit was filed, CMS issued a final decision, effective January 2016, creating "two new J Codes whose descriptors distinguish the drugs based on approved duration." *Id.* ¶ 53. And Plaintiff also admits that as soon as CMS created these new HCPCS codes, RJ Health placed the products in separate codes – causing Plaintiff to withdraw its request for injunctive relief. Am. Compl. ¶ 54. But at the time that RJ Health had to act in June 2015 to publish the lowest WAC for Code J7302, it was entirely appropriate for RJ Health to place Liletta within J7302 based on its code descriptor. In truth, RJ Health had no choice, since Liletta plainly fell within Code J7302 based on the definition established by CMS, and CMS had specifically refused to revise the Code in a way that would have excluded Liletta.

In short, RJ Health has done nothing more remarkable here than follow federal coding requirements mandated by CMS at all relevant times. Plaintiff's

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[7] *See* May 8, 2015 Public Meeting Summary, Agenda Item # 18, available at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2015-05-08-DrugAgenda.pdf.

state law claims – which are all premised on the argument that RJ Health assigned Liletta to the wrong J Code – are therefore preempted by federal law.

There are three types of preemption: express, field, and conflict. *United States v. Zadeh*, 820 F.3d 746, 751 (5th Cir. 2016). In express preemption, Congress explicitly states its intent to preempt relevant state laws. *Id.* Field preemption occurs when Congress intends to "occupy the field," taking over a field of law to the exclusion of state or local authority. *Id.* Finally, conflict preemption takes two forms: (i) when compliance with both state and federal law is impossible, and (ii) when a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* (internal quotation marks and citation omitted). Congressional purpose is " 'the ultimate touchstone' of every pre-emption case." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (citation omitted).

Here, Plaintiff's claims are expressly preempted because Congress explicitly delegated to CMS – not to private parties and not to courts applying state laws – the authority to oversee HCPCS Level II coding decisions. And Congress explicitly requires private payors, including RJ Health's customers, to adopt those same J codes in order to promote a uniform national system of coding. *See* 42 U.S.C. § 1320d-2(a)(1); 45 C.F.R. § 162.1000 – 1002.

The extensive amount of federal regulation in this area also supports field preemption. *Treasurer of N.J.*, 684 F.3d at 406 ("There is field preemption when Congress has regulated an area so pervasively that it has not left room for state regulation."). This is particularly true here, where one of the main objectives of Congress in delegating authority to HHS and CMS to oversee HCPCS codes was to create a uniform national coding system. Congress clearly intended to occupy the field in order to ensure that the system remains both uniform and national. In *Kurns v. A.W. Chesterton Inc.*, 620 F.3d 392, 398 (3d Cir. 2010), the Third Circuit held that the Congressional goal of creating national standards for the construction and design of locomotive equipment supported field preemption. As the Court noted, the relevant federal legislation was designed to "prevent the paralyzing effect on railroads from prescription by each state of the safety devices obligatory on locomotives that would pass through many of them." *Id.* (internal quotation marks and citation omitted). "If each state had its own standards for liability for railroad manufacturers, equipment would have to be designed so that it could be changed to fit these standards as the trains crossed state lines, or adhere to the standard of the most restrictive states." *Id.* Because Congress had the goal of creating a national coding system, it intended to preempt the field, in order to avoid a patchwork of conflicting state laws, and it would be inconsistent with the federal

scheme to allow state tort laws to impose liability of a firm that accurately followed CMS coding requirements.

For similar reasons, a decision based on state law imposing liability on RJ Health for its refusal to place Liletta in a different J Code would serve as an obstacle to the accomplishment of federal objectives, and would therefore be preempted under conflict preemption principles. The Congressional purpose favoring uniform national payment codes would be frustrated if each state were permitted to impose liability based on its own views of the correctness of a coding decision. For this reason, any state law that purports to weigh in on the appropriateness of a coding decision is preempted as an obstacle to the purpose of federal laws mandating a national, uniform coding system. "[A] state law cannot stand that 'either frustrates the purpose of the national legislation or impairs the efficiency of those agencies of the Federal government to discharge the duties, for the performance of which they were created.'" *Nash v. Fla. Indus. Comm'n*, 389 U.S. 235, 240 (1967) (citation omitted).

A state law claim purporting to second-guess a private party's coding decision is preempted under conflict preemption principles for another reason as well. In overseeing the HCPCS coding system, CMS is required to engage in a careful balancing of competing objectives. It would undermine federal objectives if state tort law were permitted to interfere with this delicate balancing. *See*

Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350 (2001) (state law fraud-on-the-FDA claims preempted because they necessarily interfere with FDA's ability to balance competing objectives in policing fraud); *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861 (2000) (state law requiring particular safety devices in automobiles preempted where it would interfere with the "variety and mix" of devices that could be required by federal agency).

Finally, liability under state law is barred here under conflict preemption principles because CMS had expressly ruled – twice – that the J7302 Code would *not* be reserved for Mirena alone, and would be applicable to other IUDs – like Liletta – that met the federally-established definition of that code. In this light, no state law can impose liability on RJ Health because it followed CMS coding requirements and rejected Bayer's demands that, notwithstanding CMS' actions, Liletta should be placed in a different J Code.

In short, any state law that could be used to require a defendant to place a drug in a particular J Code – particularly one that runs afoul of CMS's preliminary coding decision – is preempted by federal law.

III. PLAINTIFF'S CONNECTICUT UNFAIR TRADE PRACTICES CLAIM (COUNT II) SHOULD BE DISMISSED BECAUSE PLAINTIFF LACKS STANDING.

Plaintiff's claim under Count II for violations of the Connecticut Unfair Trade Practices Act ("CUTPA"), Conn. Gen. St. § 42–110a *et seq.*, also must be

dismissed. Plaintiff lacks standing under CUTPA because Plaintiff is not within the class of persons that CUTPA was intended to protect.

In order to demonstrate standing under CUTPA, a plaintiff must allege that it is either a consumer, a competitor, or in some type of business relationship with the defendant. *See, e.g., Suburban Properties, LLC v. Coppelman*, No. NNHCV095032489S, 2013 WL 7084801, at *16 (Conn. Super. Ct. Dec. 27, 2013) ("A party bringing [a CUTPA] claim must first establish standing under the act - that he or she is a consumer or competitor or the existence of some commercial relationship or business relationship must be shown."); *Aviles v. Wayside Auto Body, Inc.*, 49 F. Supp. 3d 216, 237 (D. Conn. 2014) ("As it is undisputed that Soto is not a consumer or competitor of Wells Fargo, nor is she in a business relationship with Wells Fargo, she has failed to establish that she has standing to maintain a CUTPA claim against Wells Fargo."); *Gilbert v. Beaver Dam Ass'n of Stratford, Inc.*, No. CV00374905S, 2001 WL 950864, at *16 (Conn. Super. Ct. July 24, 2001) ("[A] claimant under CUTPA must possess at least some type of consumer relationship with the party who allegedly causes harm to him or to her or some type of competitive or business relationship .... [I]t strains credulity to conclude that CUTPA is so formless as to provide redress to any person, for any ascertainable harm, caused by any person in the conduct of any 'trade' or 'commerce.") (internal quotation marks and citations omitted); *Bernbach v. Timex*

Corp., 989 F. Supp. 403, 412 (D. Conn. 1996) ("CUTPA liability can only arise when there is some form of commercial nexus—business competition, consumer relationships, or similar connections—linking the parties.").

The reason for this is simple. While CUTPA "gives protection to wronged competitors and consumers," it does not protect "the world at large or any individual who might be injured by the activities of a business entity no matter what relationship the individual had with that business, even no relationship at all." *Mather v. Birken Mfg. Co.*, No. CV-96-0564862, 1998 WL 920267, at *11 (Conn. Super. Ct. Dec. 8, 1998) (internal quotation marks and citation omitted). The act was not "meant to protect any individual or business who happened to be harmed no matter what the context or relationship between the wrongdoer and the claimant." *Id.* (internal quotation marks omitted).

Here, Plaintiff is neither a consumer nor a competitor of RJ Health. Nor is it in a business relationship with RJ Health. Instead, Plaintiff merely alleges injury based on RJ Health's alleged misrepresentations to third parties. Am. Compl. ¶¶ 42-47. These allegations are not enough to demonstrate standing under CUTPA. *See Gilbert*, 2001 WL 950864, at *5 (" '[I]t strains credulity to conclude that CUTPA is so formless as to provide redress to any person, for any ascertainable harm, caused by any person in the conduct of any 'trade' or

'commerce.' ") (citations omitted). Accordingly, the Court must dismiss Bayer's CUTPA claims for lack of standing.

IV. PLAINTIFF'S NEGLIGENT MISREPRESENTATION CLAIM (COUNT IV) SHOULD BE DISMISSED BECAUSE PLAINTIFF DID NOT RELY ON THE CHALLENGED STATEMENTS.

Finally, Plaintiff's amended negligent misrepresentation claim (Count IV) should be dismissed because Plaintiff has not alleged, and cannot allege, a critical element of the claim: that it relied on any alleged false statements made by RJ Health. To the contrary, Plaintiff's Amended Complaint makes clear that Plaintiff *never* relied on RJ Health's alleged misrepresentations at issue here. Am. Compl. ¶ 45 (alleging that Plaintiff "warned" RJ Health about the impropriety of its coding decision).

In order to state a claim of negligent misrepresentation under New Jersey law, a plaintiff must allege: "(1) an incorrect statement, (2) negligently made, (3) ***upon which plaintiff justifiably relied,*** and (4) resulted in economic loss or injury as a consequence of that reliance." *Mason v. Coca-Cola Co.*, 774 F. Supp. 2d 699, 704 (D.N.J. 2011) (citing *H. Rosenblum, Inc. v. Adler,* 93 N.J. 324, 461 A.2d 138, 142–43 (1983)) (emphasis added). The elements of this claim are the same under the laws of most other states, including Connecticut. *See Mara v. MacNamara*, No. 3:14-CV-01095 RNC, 2015 WL 4392956, at *11 (D. Conn. July 15, 2015) (elements of a negligent misrepresentation claim are that (1) the defendant made a

misrepresentation of fact; (2) which the defendant knew or should have known was false; (3) **the plaintiff reasonably relied on the representation**; and (4) the plaintiff suffered pecuniary harm as a result) (citing *Nazami v. Patrons Mut. Ins. Co.*, 280 Conn. 619, 626, 910 A.2d 209, 213 (2006) (emphasis added)).

Central to a negligent misrepresentation claim, then, is the requirement that *the plaintiff* must have relied on the false statement. *See Kaufman v. i-Stat Corp.*, 165 N.J. 94, 109, 754 A.2d 1188, 1195 (2000) ("The actual receipt and consideration of any misstatement remains central to the case of any plaintiff seeking to prove that he or she was deceived by the misstatement or omission"); *Karu v. Feldman*, 119 N.J. 135, 147, 574 A.2d 420, 425 (1990) ("The aggrieved party must be a reasonably foreseeable recipient of the company's statements for its proper business purpose, who relies on the statements.").[8]

Failure to allege that the plaintiff relied on the defendant's allegedly false statement warrants dismissal of a negligent misrepresentation claim. For example, in *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action,* No. 2:06-CV-5774(SRC), 2009 WL 2043604, at *33 (D.N.J. July 10, 2009), the court dismissed a negligent misrepresentation claim where "the only colorable allegations by Plaintiffs of receipt and reliance concern the generic allegations,

[8] Although this contention was briefed on the prior motion to dismiss, the Court's June 30 opinion noted expressly that the Court "d[id] not reach" this issue. June 30 Op. at 10.

repeated throughout the Complaint, that unnamed doctors, not Plaintiffs, relied on Schering's misrepresentations . . . ." *See also Carroll v. Cellco P'ship,* 313 N.J. Super. 488, 503, 713 A.2d 509, 516 (App. Div. 1998) (recognizing the importance of a plaintiff's reliance to a negligent misrepresentation claim in denying class certification, noting that "plaintiffs must prove that varying communications to plaintiffs were negligently made and that *each plaintiff relied upon them*, thus resulting in an ascertainable loss.") (emphasis added*); accord Gross v. Johnson & Johnson-Merck Consumer Pharm. Co.,* 303 N.J. Super. 336, 349, 696 A.2d 793, 799 (Law. Div. 1997).

Courts in other jurisdictions have taken a similar approach. Thus, in *Cahill v. Eastern Benefit Systems, Inc.*, 236 Ill. App. 3d 517, 521, 603 N.E.2d 788, 792 (1992), an Illinois Court of Appeals affirmed dismissal of a negligent misrepresentation claim where the plaintiff alleged that his insurer relied on the allegedly false statement. *See also, e.g., Fed. Treasury Enter. Sojuzplodoimport v. Spirits Int'l N.V.*, 400 F. App'x 611, 613 (2d Cir. 2010) ("fraud claims may not be premised on false statements on which a third party relied"); *Westwood-Booth v. Davy-Loewy Ltd.,* No. CIV. A. 97-7539, 1999 WL 219897, at *4 (E.D. Pa. Apr. 13, 1999) ("A plaintiff cannot state a claim for fraud based on a third party's reliance

on a misrepresentation, even when it was made to influence the third party foreseeably to act in a manner detrimental to the plaintiff.").[9]

Here, although Plaintiff has attempted to amend its Complaint to include specific allegations of reliance, those new allegations only serve to make abundantly clear that Plaintiff's real allegation is that third party payors—not Plaintiff—relied on RJ Health's alleged misrepresentations. As amended, Plaintiff's allegations regarding reliance are as follows:

- "Payors reasonably relied on RJ Health's misrepresentations in making their reimbursement decisions, because RH [sic] Health holds out its products as the industry standard for claim coding and processing."

- "Payors relied on RJ Health's misrepresentation regarding the 'code price' for Mirena in lowering the amount they reimburse healthcare provides for purchases of Mirena."

Am. Compl. ¶¶ 90-91. But Plaintiff must claim that *it*—not some other entity—relied on the alleged misstatements. Plaintiff has not and cannot do so. Accordingly, Plaintiff's claim for negligent misrepresentation must be dismissed. *See, e.g., In re Schering-Plough Corp.*, 2009 WL 2043604, at *33.

And this time, dismissal should be with prejudice. Where, as here, a plaintiff has "already amended [its] pleading once, and despite being given a

[9] The standard for reliance in a negligent misrepresentation claim is the same as the reliance standard applicable in a fraud claim. *See Johnson v. Draeger Safety Diagnostics, Inc.*, No. 13-2439 (JLL), 2013 WL 3788937, at *7 (D.N.J. July 19, 2013) (the "element of reliance is the same for fraud and negligent misrepresentation" (internal quotation marks and citation omitted)).

second bite at the apple, [it] has been unable to cure the deficiencies in [its] original Complaint," further amendment would be futile and dismissal should be with prejudice. *Trumper v. GE Capital Retail Bank*, 79 F. Supp. 3d 511, 513 (D.N.J. 2014) (citing *Grayson v. Mayview State Hosp.*, 293 F.3d 103, 108 (3d Cir. 2002).

CONCLUSION

For the foregoing reasons, Plaintiff's First Amended Complaint should be dismissed in its entirety, with prejudice.

Dated: August 29, 2016

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